

Effectiveness of Chlorhexidine and aloe vera mouthwash in patients with periodontal disease: A randomized controlled trial

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Effectiveness of Chlorhexidine and aloe vera mouthwash in patients with periodontal disease: A randomized controlled trial

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ABSTRACT

Background. Aloe vera has gained significant attention in clinical research, and promoting natural substances is a prevailing trend in dentistry.

Aim. This study compares the effectiveness of Aloe vera mouthwash and 0.2% chlorhexidine gluconate mouthwash in reducing plaque buildup and gingivitis.

Materials and Methods. A single-blind trial included 270 volunteers who were systemically healthy and aged between 18 and 45 years. The participants were randomly assigned to three groups: Group A (test group) received Aloe vera mouth rinse, Group B (the positive control group) received a placebo (distilled water), and Group C (the negative control group) received 0.2% chlorhexidine. Clinical indicators, which include the Plaque Index (PI) by Sillness and Loe in 1964 and the Gingival Index (GI) by Loe and Sillness in 1963, were evaluated at baseline, day 15, and day 30 for all three groups. Participants were directed to rinse their mouths with the specified mouthwash twice daily for 30 days.

Results. A significant reduction in plaque index (PI) and gingival index (GI) scores was observed after starting the rinse regimen in Group A (Aloe vera group) and Group C (Chlorhexidine) compared to Group B (placebo group). There was no significant difference between the Aloe Vera and chlorhexidine groups ($p < 0.05$).

Conclusion. This study confirms the efficacy of Aloe vera mouthwash as an antiplaque agent. Aloe vera mouthwash has the potential to become a cost-effective herbal substitute for Chlorhexidine, with enhanced flavor and longer shelf life. This rinse is a cost-effective, long-term solution for preventing plaque buildup and treating gingivitis.

Keywords: Aloe vera, Chlorhexidine, Periodontal Disease, Plaque index, Mouthwashes

Introduction:

Herbal and natural products are increasingly used in dentistry to treat various oral diseases and conditions. Numerous plant-based solutions have antibacterial properties and are highly effective at teeth cleaning. For comparable reasons, these alternatives are valuable options instead of traditional antibiotics and antimicrobials [1-4].

Maintaining periodontal health is a crucial part of total dental health. Plaque-induced gingivitis, which affects more than 90% of the population, highlights the importance of preventive oral care [5]; if not properly treated, plaque-induced gingivitis can develop into periodontal disease. Symptoms of gingivitis caused by plaque include swollen and red gums and bleeding easily during brushing or flossing. When inflammation spreads to the supporting structures of teeth, it

can cause bone defects in the periodontal area, ultimately leading to tooth loss [6]. The primary objective in preventing periodontal diseases is to control plaque formation and manage gingivitis through individual oral hygiene practices and regular professional evaluations and maintenance when necessary [7]. However, completely eradicating bacterial plaque presents challenges, making it essential to reduce plaque accumulation or modify its composition to prevent periodontal disease [8].

It is necessary to properly control plaque using mechanical and chemical approaches to prevent periodontal diseases. Chlorhexidine (CHX) is considered the most effective method for chemical plaque treatment because of its strong antibacterial properties and ability to decrease plaque buildup. Long-term use of Chlorhexidine is limited because of its adverse effects, such as discoloration of dental materials and teeth, erosion of the tongue and mucosa, a peculiar or unpleasant taste in the mouth, and increased buildup of supragingival calculus [9,10].

As concerns grow over the harmful effects of chemical mouthwashes, there is a growing interest in exploring herbal alternatives with antibacterial and anti-inflammatory properties. Aloe vera mouthwash is one such option that can aid in controlling plaque and treating gingivitis, with the added advantage of having no discernible side effects [2,10].

The pharmacological advantages of aloe vera are derived from its multifaceted characteristics, including wound-healing, immunomodulatory, anti-inflammatory, antioxidant, and antimicrobial features [11]. Furthermore, Aloe vera exhibits properties that reduce edema by inhibiting matrix metalloproteinases, blocking obstruction of polymorphonuclear leukocyte (PMN) release, and modulating the cyclooxygenase and lipoxygenase pathways. Consequently, activated PMNs inhibit free oxygen radical activity [12].

Although the therapeutic attributes of Aloe Vera have been widely recognized, there is a need for additional scholarly research on its utilization as a dental mouthwash. This study compares Aloe Vera and chlorhexidine mouthwash to analyze their impact on periodontal health. It aims to provide insights into their benefits in promoting oral hygiene and preventing periodontal diseases.

Materials and Methods:

The study was a 30-day single-blind, randomized, parallel, controlled clinical trial. This study aimed to assess and contrast the efficacy of Aloe vera mouthwash with 0.2% chlorhexidine gluconate mouthwash in reducing plaque accumulation and alleviating gingival inflammation.

-Study population

The study recruited 270 systemically healthy subjects with moderate to severe gingivitis. Of the participants, 144 were females, and 126 were males between 18 and 45. The participants were selected randomly from the outpatient sector of the Azadi and Hawler Centers in Erbil City, Kurdistan Region, Iraq. The study took place between April 1 and October 1, 2023.

The study was approved by the Ethical and Scientific Committee of the Kurdistan Higher Council of Medical Specialties in a letter dated August 12, 2022, with reference number (2276).

The volunteers were fully informed about the methodology employed in the clinical trial before providing their informed written consent. The participants received sufficient information about their ability to withdraw from the study at any time while it was being conducted.

- Inclusion criteria

After a comprehensive clinical evaluation and review of medical history, individuals in good systemic health who had not previously undergone treatment for plaque-induced gingivitis became eligible for the study upon meeting the following inclusion criteria:

- Moderate to severe gingivitis (gingival index score greater than 1) was detected in participants, who ranged in age from 18 to 45.
- At least 20 natural teeth were present in the participants, at least five in each mouth quadrant.
- Participants agreed to participate in the study and provided their signature on the consent form.

- Exclusion criteria

Participants who fulfilled any of the following criteria were not included in the study:

- (1) probing pocket depth ≥ 3 mm;
- (2) receiving antibiotic medication within one month of the trial;
- (3) Using anti-inflammatory dental products or mouth rinses regularly;
- (4) smokers and

tobacco consumers; (5) lactating and pregnant women; (6) any orthodontic appliances or those with a removable and fixed prosthesis that may interfere with the evaluation; (7) severely misaligned teeth; (8) participants having medical conditions that could negatively impact the study results; (9) had undergone periodontal treatment in the past 15 days; (10) participants who have known allergy to any of the substances used in the study.

-Study tool

The data-gathering procedure used a proforma that was split into two sections. The initial element of the proforma included a structured interview segment that collected data on demographic information, oral hygiene habits, and the medical and dental backgrounds of the participants. This section's portion aimed to gather relevant background information on the participants.

Part two of the proforma comprised the clinical assessment of periodontal health. The study reported the following clinical parameters:

- The plaque index, developed by Sillness and Loe in 1964 [13], was utilized to quantify the degree of plaque buildup on the teeth.

- ²⁰ The gingival index, developed by Loe and Sillness in 1963 [14], assessed the extent of gingivitis by investigating the state of gingival tissue. Variables, including redness, edema, and bleeding.

Baseline assessments were performed on all individuals before administering the mouthwashes. The efficiency of the mouthwashes was evaluated by examining follow-up after 15 and 30 days, considering the dependent variables. The tools utilized to record indices included a ⁴⁰ mouth mirror, an explorer, a periodontal probe, and tweezers. ¹ Four surfaces (buccal, lingual/palatal, mesial, and distal) of six specified index teeth (18, 23, 26, 38, 43, 46) were assessed throughout the examination. An evaluation was performed on the ² dental plaque index (PI) and gingival index (GI) by inspecting ¹ the four surfaces of the index teeth to determine the presence or absence of signs linked to these indices.

A calibrated periodontal probe was utilized to evaluate the sites during the examination, with a ¹ 10-second interval allowed to confirm the presence or absence of gingival bleeding. Plaque

detection was done by directly observing or detecting the soft matter deposited along ¹the gingival margin and in the tooth and gingival pocket. Plaque Index scores of 2 and 3 were assigned accordingly. Dental plaque was deemed present if the distinctive indication was observed in ¹at least one location. PI was classified as follows: Healthy = PI < 1; Fair = PI 1–1.9; Bad = PI ≥ 2.

¹Gingivitis was diagnosed if there was bleeding at a single site during inspection, corresponding to scores 2 and 3 on the GI index. The gingival index quantified the severity of gingivitis on a scale ranging from 0.1 to 3.0, with specific classifications: 0.1–1.0, mild gingivitis; 1.1–2.0, moderate gingivitis; and 2.1–3.0, severe gingivitis. Gingivitis was classified as moderate or severe if the gingival index exceeded 1, computed as the average value of all tooth surfaces assessed.

- Out of the 324 participants initially screened, 300 individuals with gingivitis were selected and enrolled in this clinical study, following the specified inclusion and exclusion criteria. The participants underwent professional dental cleaning (²scaling and polishing) one week before the start of the clinical research and were advised to continue their usual oral care routine. However, by the end of the 7 days, 30 participants withdrew from the study for numerous reasons.

A total of 270 volunteers including (126 males and 144 females) ³⁰were randomly allocated to three groups using a computer-generated random table approach. Groups were allocated based on the type of mouthwash used.

- Group A (n=90): Test group, which received a commercially available Aloe vera mouthwash (0% Alcohol, Aloe Barbadense Leaf juice, Aqua, Sorbitol, Sodium Fluoride: 226 ppm F-, Glycerin, Xylitol, Mint Flavor, ASIN: B00L7QP7WM).
- Group B (n=90): The negative control group was given a ³Placebo distilled water mouthwash.
- Group C (n=90): The positive control group was given 0.2% chlorhexidine mouthwash. (Pattnaik et al., 2021)

The mouthwashes were administered in identical containers with opaque coverings to ensure single blinding. Each participant was given written instructions regarding using the mouth rinse properly.

All three groups received the exact ⁴⁶oral hygiene instructions during the study, except for using the allocated mouth rinse. A container bearing an indistinguishable appearance was provided to every participant, which contained 500 ml of the mouthwash solution. A calibrated measuring cup featuring a 10 ml capacity was furnished to guarantee a precise dosage.

All participants were directed to cleanse their mouths twice daily ³⁷for one minute with 10 ml of the designated ³⁷solution across all groups. ³⁷The prescribed rinsing routine was to be executed regularly for 30–45 minutes, once in the morning and once before nightfall, for 30 days. Furthermore, participants were instructed to abstain from eating or cleansing with other substances for 30 minutes after using mouthwash.

Participants were prohibited from using additional oral hygiene products or procedures during the study, including interdental simulators or dental floss.

On the 15th and 30th day following baseline, clinical evaluations of ²⁶the gingival index (GI) and ²⁶plaque index (PI) were performed and compared to the evaluations of gingivitis and dental plaque at baseline. Participants were directed to return their bottles to document the leftover rinse solution, guaranteeing adherence to the rinsing process. All subjects followed the rinsing instructions precisely, with no variations in the frequency or amount of mouthwash.

⁴²**Statistical analysis**

The collected data underwent statistical analysis using SPSS software version 26. ¹⁶Categorical variables were analyzed using Chi-square and Fisher's exact tests. Repeated measures analysis was conducted on consecutive continuous variables, followed by multiple comparisons using a ⁴³post hoc test. A ⁴³p-value of 0.05 or below signifies statistical significance.

Results

The study involved 270 healthy participants divided into three groups: 90 received Aloe vera, 90 received chlorhexidine, and 90 received Placebo. ¹²No statistically significant differences in ⁴⁵age ($p=0.06$) or gender ($p=0.9$) between the study groups. (Table 1)

Table 1: Distribution of demographic characteristics according to study groups.

Variable	Study groups						p-value
	Aloe vera		Chlorhexidine		Placebo		
	No.	%	No.	%	No.	%	
Age							
<20 years	1	1.1	8	8.9	9	10.0	0.06
20-29 years	31	34.4	40	44.4	35	38.9	
30-39 years	46	51.1	29	32.2	36	40.0	
≥40 years	12	13.3	13	14.4	10	11.1	
Gender							
Male	43	47.8	42	46.7	44	48.9	0.9
Female	47	52.2	48	53.3	46	51.1	

*Chi-square test, **Significant at $p \leq 0.05$

The study groups had no significant differences regarding the baseline plaque index ($p=0.7$) and gingival index ($p=0.3$). (Table 2)

Table 2: Distribution of baseline oral health measures according to study groups.

Variable	Study groups						p-value
	Aloe vera		Chlorhexidine		Placebo		
	No.	%	No.	%	No.	%	
Baseline PI							0.7
Fair	47	52.2	51	56.7	46	51.1	
Bad	43	47.8	39	43.3	44	48.9	
Baseline GI							0.3
Mild	2	2.2	6	6.7	5	5.6	
Moderate	86	95.6	79	87.8	83	92.2	
Severe	2	2.2	5	5.6	2	2.2	

*Chi-square test, **Fishers exact test, ***Significant at $p \leq 0.05$.

After a 30-day treatment with Aloe vera mouthwash, there were significant decreases in the mean of GI and PI ($p < 0.001$). Significant decreases in the gingival index (GI) and plaque index

(PI) were distinguished following 30 days of Chlorohexidine mouthwash use ($p < 0.001$). Similarly, using placebo mouthwash for 30 days resulted in prominent reductions in both GI and PI ($p < 0.001$) (Table 3).

Table 3: Distribution of oral health measures according to study durations for different study groups.

Study groups	Study durations			p-value
	Baseline Mean \pm SD	At 15 th day Mean \pm SD	At 30 th day Mean \pm SD	
Aloe vera group				
Plaque index	1.9 \pm 0.3	1.6 \pm 1.5	1.07 \pm 0.2	<0.001
Gingival index	1.5 \pm 0.2	1.1 \pm 0.2	0.7 \pm 0.2	<0.001
Chlorhexidine group				
Plaque index	1.9 \pm 0.4	1.5 \pm 0.3	1.03 \pm 0.2	<0.001
Gingival index	1.5 \pm 0.3	1.09 \pm 0.2	0.6 \pm 0.2	<0.001
Placebo group				
Plaque index	1.9 \pm 0.3	1.7 \pm 0.3	1.6 \pm 0.3	<0.001
Gingival index	1.5 \pm 0.3	1.4 \pm 0.3	1.3 \pm 0.3	<0.001

*Repeated measures analysis, **Significant at $p \leq 0.05$.

By post hoc analysis, the means of PI index for participants with Aloe vera mouthwash and Chlorohexidine mouthwash were not significantly different ($p = 0.8$). In contrast, the means of PI index for participants with Aloe vera mouthwash were significantly lower than the PI means of participants with placebo mouthwash ($p < 0.001$), and the means of PI index for participants with Chlorohexidine mouthwash were significantly lower than the PI means of participants with placebo mouthwash ($p < 0.001$) (Table 4).

Table 4: Multiple comparisons of plaque index between study groups.

Multiple Comparisons					
Study	Compared	Mean	Std.	p-	95% Confidence

groups	groups	Difference	Error	value	Lower Bound	Upper Bound
Aloe vera	Chlorhexidin	0.03	0.06	0.8	-0.11-	0.17
	Placebo	-0.23-	0.06	<0.000	-0.38-	-0.09-
Chlorhexidine	Aloe vera	-0.03-	0.06	0.8	-0.17-	0.11
	Placebo	-0.26-	0.06	<0.000	-0.41-	-0.12-
Placebo	Aloe vera	0.23	0.06	<0.000	0.09	0.38
	Chlorhexidin	0.26	0.06	<0.000	0.12	0.41

* Tukey HSD, S=Significant, **Significant at $p \leq 0.05$.

By post hoc analysis, the means of GI index for participants with Aloe vera mouthwash and those with Chlorohexidine mouthwash were not significantly different ($p=0.6$). In contrast, the means of GI index for participants with Aloe vera mouthwash was significantly lower than the GI means of participants with placebo mouthwash ($p < 0.001$), and the means of GI index for participants with Chlorohexidine mouthwash were significantly lower than the GI means of participants with placebo mouthwash ($p < 0.001$) (Table 5).

Table 5: Multiple comparisons of gingival index between study groups

Multiple Comparisons						
Study groups	Compared groups	Mean Difference	Std. Error	p-value	95% Confidence Interval	
					Lower Bound	Upper Bound
Aloe vera	Chlorhexidin	0.03	0.041	0.6	-0.06-	0.13
	Placebo	-0.29-	0.041	<0.000	-0.38-	-0.19-
Chlorhexidine	Aloe vera	-0.03-	0.041	0.6	-0.13-	0.06
	Placebo	-0.32-	0.041	<0.000	-0.42-	-0.22-
Placebo	Aloe vera	0.29	0.041	<0.000	0.19	0.38
	Chlorhexidin	0.32	0.041	<0.000	0.22	0.42

* Tukey HSD, **Significant at $p \leq 0.05$.

There was a highly significant difference in PI on the 30th day between study groups ($p < 0.001$); 25.6% of Aloe vera participants had healthy PI, 43.3% of Chlorhexidine participants had healthy PI, and only 5.6% of placebo participants had healthy PI. There was a highly significant difference in GI on the 30th day between the study groups ($p < 0.001$); 95.6% of Aloe vera participants had mild gingivitis, and 96.7% of Chlorhexidine participants had mild gingivitis, while only 27.8% of placebo participants had mild gingivitis (Table 6).

Table 6: Distribution of oral health measures on the 30th day according to study groups.

Variable	Study groups						p-value
	Aloe vera		Chlorhexidine		Placebo		
	No.	%	No.	%	No.	%	
PI on the 30th day							<0.001
Healthy	23	25.6	39	43.3	5	5.6	
Fair	67	74.4	50	55.6	76	84.4	
Bad	0	-	1	1.1	9	10.0	
GI on the 30th day							<0.001
Mild	86	95.6	87	96.7	25	27.8	
Moderate	4	4.4	3	3.3	64	71.1	
Severe	0	-	0	-	1	1.1	

* Fisher's exact test, **Significant at $p \leq 0.05$

Discussion

Over the past few years, dentistry has experienced a discernible shift toward applying several herbal and natural products to treat oral diseases and conditions. Numerous plant-derived products possess antimicrobial and teeth-cleansing properties, offering practical alternatives to conventional antibiotics and antimicrobials commonly used for similar purposes [15]. Moreover, Herbal treatment has a lower risk of side effects over a long period than traditional

pharmaceuticals [16]. Aloe Vera is a potent antibacterial agent that efficiently fights bacteria and helps prevent gingival and periodontal diseases [1,16].

The study revealed ¹ a significant decrease in the mean scores of the gingival and plaque indices after a 30-day treatment with Aloe vera mouthwash ($p < 0.001$). The findings align with the quasi-experimental study by Hamonari et al. [2]; it showed reduced gingival and plaque indices ⁴⁸ associated with periodontal disease. In addition, a recent ²⁷ randomized controlled experiment confirmed these results by comparing the antiplaque and anti-gingivitis efficacy of Chlorhexidine and Aloe vera mouthwash in patients with fixed orthodontics [4].

An additional double-blind placebo-controlled clinical investigation conducted in Iran, as reported by Yaghini et al. demonstrated a reduction in the mean values of the gingival and plaque indices following two weeks of Aloe vera mouthwash usage [17].

This study used chlorhexidine-containing mouthwash as a positive control, following the approach of several prior studies that compared it with other mouthwash products [3,4,18]. Chlorhexidine (CHX) is highly regarded as the most effective treatment because of its outstanding ability to prevent plaque buildup and fight against microorganisms [3,4,18,19]. According to the current ² study, there was a statistically significant reduction in the means of the gingival and plaque index following a 30-day treatment with chlorhexidine mouthwash ($p < 0.001$). The results of this research align with the findings of a ⁷ study conducted in the United States of America by Sreenivasan and Prasad); the study reported that within two weeks, ⁴⁹ the use of chlorhexidine mouthwash led to substantial decreases in both ¹⁵ the gingival index and plaque index [19].

This study observed ³¹ a significant reduction in the mean gingival and plaque index after 30 days of using a placebo mouthwash ($p < 0.001$). This finding aligns with the Gupta ¹⁵ et al. double-blind, randomized controlled experiment conducted in India, which observed significant decreases in gingival and plaque index after 30 days of using a placebo mouthwash [10]. Xu et al. conducted a randomized controlled experiment in China, which found that daily water mouthwash reduced gingival and plaque index by altering oral microbiota from anaerobic to aerobic phenotypes [20].

According to the study findings, there was no statistically significant difference ($p=0.8$) in the mean plaque index (PI) values between participants who utilized chlorhexidine mouthwash and those who used aloe vera mouthwash. This study is consistent with the results of the Yeturu et al. randomized controlled trial conducted in India, which revealed a prominent reduction in plaque index after 15 days of using mouthwash containing Aloe vera and Chlorohexidine, with no significant differences between the two [21], which observed a substantial reduction in plaque index following 15 days of using mouthwash containing both chlorohexidine and aloe vera. Distinction between the two substances was not statistically significant. Nevertheless, the study findings indicated that the PI index means of participants who used Aloe vera mouthwash and Chlorohexidine were considerably reduced compared to those who used placebo mouthwash ($p<0.001$). This finding aligns with the outcomes of the Alnouri et al. randomized controlled trial conducted in Syria, which demonstrated a notable disparity in Plaque Index (PI) between children using Aloe vera mouthwash and Chlorohexidine mouthwash compared to those using a placebo mouthwash [18]. This finding aligns with the outcomes documented in a review study conducted in Iran by Poorkazemi et al., which proposed that Aloe vera mouthwash might reduce the gingival index to a degree comparable to chlorohexidine mouthwash.

The results of this research indicated that the participants who used mouthwash containing Aloe vera and chlorohexidine had significantly reduced mean GI indices than those who used placebo mouthwash ($p<0.001$) [22].

The results align with the conclusions drawn by Vangipuram et al. in their randomized controlled trial conducted in India. The effectiveness of a mouthwash containing Chlorhexidine and aloe vera in reducing the gingival index was superior to that of a placebo [1].

The study found a significant difference in plaque index (PI) on the 30th day among study groups ($p<0.001$): 25.6% of Aloe vera participants had healthy PI, 43.3% of Chlorohexidine participants had healthy PI, and only 5.6% of placebo participants had healthy PI. The findings are consistent with those of Al-Maweri et al., who conducted a comprehensive review to assess the efficacy of mouthwash containing aloe vera against gingival inflammation and plaque. The review found that aloe vera mouthwash is as beneficial as Chlorhexidine in reducing gingival inflammation. However, it could be more effective [11].

The study found a significant difference in GI on the 30th day between trial groups ($p < 0.001$), with 95.6% of Aloe vera participants and 96.7% of Chlorohexidine participants experiencing mild gingivitis, compared to only 27.8% of the placebo group. These results are consistent with Parker et al.'s randomized controlled trial study in India, which revealed that chlorohexidine mouthwash was more efficient than aloe vera mouthwash in reducing gingivitis [23].

Conclusion

Aloe vera mouthwash aids in treating periodontal diseases. Aloe vera mouthwash effectively reduces plaque and gingival indices. However, Chlorohexidine mouthwash is more effective than Aloe vera mouthwash. This study recommended using Aloe vera mouthwash as an alternative treatment for periodontal diseases.

Conflicts of Interest: No conflicts of interest exist.

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